

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

3-05

☐ Other ☐ Amendment Number:

Contract Number

EP-W-11-020

Contract Period 02/01/2011 To 01/31/2015

Base Option Period Number 3

Title of Work Assignment/SF Site Name

DER Production AD

Contractor

CDM FEDERAL PROGRAMS CORPORATION

Specify Section and paragraph of Contract SOW

Section III Task A

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 02/01/2014 To 01/31/2015

Comments:

In accordance with contract clause B.2 "Work Assignments", please submit a detailed work plan and cost estimate to the Contracting Officer (CO) and Contracting Specialist (CS) within fourteen (14) calendar days after receipt of this work assignment initiation. The work plan shall include a detailed technical and staffing plan with incorporated QA elements.



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee:

LOE:

02/01/2011 To 01/31/2015

This Action

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Srinivas Gowda

Branch/Mail Code:

Phone Number 703-308-6354

FAX Number:

(Signature)

(Date)

Project Officer Name Tanisha Brockett

Branch/Mail Code:

Phone Number: 703-305-6937

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name Christine Edwards

Branch/Mail Code:

Phone Number: 202-564-2182

FAX Number:

(Signature)

(Date)

WA-3-05

STATEMENT OF WORK

I: TITLE

Technical Support to Review and Evaluate Environmental Fate, and Ecological Effects Data on Antimicrobial Pesticides for Registration/Registration Review

II: WORK ASSIGNMENT MANAGER

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III: LEVEL OF EFFORT

Labor Hours: 750 Hours
Duration: February 1, 2014 thru January 31, 2015

IV: BACKGROUND

EPA's Office of Pesticide Programs (OPP) as required by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996, institutes procedures for the registration of pesticides. OPP develops data requirements and study guidelines that are

used to assess the potential impact pesticides may have on human health and the environment. Before using these data for regulatory purposes, OPP must evaluate the studies to determine their adequacy and to guarantee that appropriate quality assurance (QA) procedures were carried out. OPP also convenes workshops and seminars to discuss and resolve scientific issues related to the registration of pesticides.

V: PURPOSE

The purpose of this work assignment is to provide technical expertise for the review and evaluation of Ecological Effects, Environmental Fate, and Transport data to assist EPA in meeting its legislative mandates. To support EPA's OPP AD, the contractor shall review and evaluate Environmental Fate, and Ecological Effects studies. The studies are conducted in accordance with OPP's Subdivisions E, J, L, and N Test Guidelines and may include data on the other special for data evaluations. The contractor shall conduct expert reviews of complex science issues and perform data extraction/entry from ecotoxicological data summaries, using computerized data bases.

Under Contract No.: EP-W-110-20, provide technical support for the Antimicrobial pesticide registration/registration review process in the areas of Environmental Fate, and Ecological Assessments of pesticides. This Work Assignment will be for conducting new work anticipated by EPA's OPP, AD, and the contractor shall not duplicate any work that was conducted under any of the previous Work Assignments under this contract.

The Tasks described in this Statement of Work/Work Assignment do not involve laboratory work or practical analysis. References to, "the development of methods", refers to the contractor reviewing and providing EPA with data and information from peer-reviewed literature and other scientifically credible sources that can be used to develop or modify existing methods. References to "evaluation" or "analysis" refers to the review of data and information using scientifically sound and accepted principles in the areas of Environmental Fate and Ecological Effects.

In instances where the Antimicrobials Division (AD) intends to use the Contractor to review or analyze FIFRA Confidential Business Information (CBI), AD will make arrangements to have the Contractor and pertinent sub-contractors cleared to handle CBI.

VI: GENERAL REQUIREMENTS

To perform Work Assignments under this contract, the contractor may require access to FIFRA Confidential Business Information (FIFRA CBI) submitted by pesticide registrants to EPA. Disclosure of FIFRA CBI to contractors is provided for under Section 10(e) of FIFRA and in 40 CFR 2.307. Consequently, the contractor must be cleared for access to FIFRA CBI and must control FIFRA CBI according to the requirements specified for contractors in the EPA publication, "FIFRA Information Security Manual", dated July 1988. Access of the contractor to FIFRA CBI is intermittent and will not require allocation of office space. Identification of contractor personnel will be made by EPA while on site at EPA.

Control measures for protecting FIFRA CBI shall be in accord with the following sections of the Security Manual:

- "Disclosure of FIFRA CBI to contractors," Section 3;
- "Procedures for Gaining Access to FIFRA Sensitive Information," Section 4; and
- "Operational Procedures for Protecting FIFRA Sensitive Information," Section 5.

The contract, as written, shall incorporate certain clauses that describe actions to be taken by the contractor with regard to FIFRA sensitive information; these clauses are contained in **40 CFR 2.301 (h)(23)(ii)**, and are Exhibit 6 in the Security Manual.

In evaluating and performing services required under this Work Assignment (WA), the contractor shall submit all relevant information used in developing conclusions or options to the cognizant Work Assignment Manager (WAM) for all projects for review and approval.

All reports, drafts, papers etc. prepared by the contractor shall be submitted in draft form. The contractor shall submit the competed draft to the WAM for review and approval. The drafts submitted shall include copies of the literature cited or make reference to all citations in the document for WAM verification and approval.

When in attendance at meetings, the contractor's attendance shall be limited to that portion of the activity for which the contractor is required in order to meet the requirements of the SOW. The contractor personnel shall identify themselves as contractor personnel in all activities associated with work performed under the SOW, and in attendance at meetings in conjunction with activities with the SOW requirements.

Reports submitted by the contractor that contain recommendations to the Agency (which will be used by EPA personnel in developing policy), will explain and rank policy or action alternatives, if any; describe the procedures used to arrive at recommendations, summarize the substance of deliberation; report any dissenting views; list the sources relied upon; and make clear the methods and considerations upon which the recommendations are based.

VII: SCOPE OF WORK

The contractor shall supply the necessary labor, materials, equipment, services and facilities (except as otherwise specified) required for the performance of each work assignment. The scientific quality of assessments and reports and their timely preparation in accordance with negotiated schedules are of paramount importance in the performance of this contract. Consequently, the contractor shall have the necessary technical and scientific knowledge and experience to work effectively from contract start-up and throughout the course of the contract. In addition, the contractor shall have a Quality Assurance (QA) / Quality Control (QC) program

that maintains the quality of products. Performance of work under this WA will encompass tasks in one or more of the following areas: Environmental Fate and Ecological Effects.

VIII: TASKS/SCIENCE AREAS

TASK 1: ENVIRONMENTAL FATE SUPPORT

This procurement will provide for the evaluation of data pertaining to the chemistry and fate of pesticides in the environment for registration and special review activities. The contractor shall evaluate individual studies of environmental fate processes, and shall identify any variance from published guidelines/standards, evaluation practices/data review guidelines, etc. OPP will use the review results to support its environmental exposure assessment used in making regulatory decisions. The data requirements to support registration are delineated in 40 CFR part 158, Guidelines for Registering Pesticides in the United States 1982, Subpart N and other applicable documents.

Task 1-1: Registration and Registration Review Support

For the registration and registration review of specific pesticide products, including new uses for currently registered products and new pesticides, OPP has the responsibility of determining data gaps, reviewing chemistry and fate data submitted with applications, and developing summaries of the environmental fate data. The contractor shall provide support for these activities, which may include statistical evaluation of environmental fate data, review of data submitted in support of registration and preparation of fate characteristics and summaries, using formats provided by the Agency.

The contractor shall review data summaries and reformatted existing studies to identify data gaps and any studies that indicate adverse effects and conduct a thorough, comprehensive examination of all chemistry and fate data of the pesticides under review. Based on these reviews and thorough examination of the data, the contractor shall prepare documented compilations of the current knowledge of the chemistry and fate resulting from the use of each specific pesticide, and shall describe additional data needed to support continued use of said pesticide, if any.

Subtask 1-1-1: Review and Evaluation of Environmental Fate Chemistry Data

The contractor shall perform critical reviews of each study furnished to them, and these reviews shall be provided to EPA's Project Officer. Each review shall encompass all items in the study that contribute to the overall knowledge of the pesticide, and shall include the following:

- 1) an evaluation of the accuracy and credibility of that study;
- 2) its suitability for meeting data requirements; and

- 3) any necessary graphic displays of data, and/or summary tables necessary to allow one to reach an independent conclusion about the results of the study.

These reviews shall be sufficiently complete in description and technical data to stand on their own as a source of information for use in OPP exposure assessment. These documents will be called DERs (data evaluation records) In all cases where part or all of a study is considered to be unacceptable because of variance from the guidelines or on technical or scientific grounds (reliability or completeness), the contractor shall explain the specific reasons for making such a conclusion. The contractor shall also explain if deficiencies in the study can be addressed with additional information from the registrant, or if a new study is required. The major areas for consideration for specific studies listed below include: hydrolysis, photolysis, metabolism, mobility, field dissipation, accumulation studies, and biomonitoring/monitoring.

A) 835.2120/161-1-Hydrolysis

B) 835.2240/161-2 - Photolysis (aqueous solution)

835.2410/161-3 (soil photolysis)

835.2370/161-4 (air photolysis)

C) Biodegradation – Laboratory

(1) 835.1100-Activated Sludge Sorption isotherm

(2) 835.3110-Ready Biodegradability

(3) 835.3220-Porous Pot Study or (GLN 835.3280) Simulation Tests to Assess the Biodegradability of Chemicals Discharged to Wastewater or (GLN 835.3240) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units.

(4) 850.6800-Modified Activated Sludge, Respiration Inhibition Test

D) Metabolism

(1) Soil

(a) 835.4100/162-1-Aerobic

(b) 835.4200/162-2-Anaerobic

(2) Aqueous

(a) 835.4400/162-3-Anaerobic

(b) 835.4300/162-4-Aerobic

E) Mobility

(1) 835.1230; 835.1240/163-1- Leaching/Adsorption/Desorption

(a) 835.1230- batch equilibrium

- (c) 835.1210-Soil Thin-Layer Chromatography
- (b) 835.1240-Soil column leaching

(2) Volatility

- 835.1410/163-2 - Volatility (laboratory) and
- 835.8100/163-3 Volatility (field)

(3) Special Leaching Study (Aqueous Availability) (antifoulants: ASTM 6903-07; wood preservatives: American Wood Preservers Association's (AWPA's), Standard Method Of Determining The Leachability of Wood Preservatives, E11-06).

4) Any protocols developed by industry in conjunction with the Agency

E) Field Dissipation -- 835.6200/164-1 through 164-5 -- Soil (includes aquatic sediment and dissolved sediment), water column, forest ecosystem (foliage, leaf litter, exposed and litter-covered soil, standing/moving water, pond/stream sediment).

F) Accumulation Studies -- 165-4 (fish) and 165-5 (aquatic non-target)

- (1) Bioaccumulation in fish -- 165-4 (laboratory studies)
- (2) Bioaccumulation in aquatic non-target organisms -- 165-5 (field studies)

G) Biomonitoring/monitoring of representative sites (e.g., freshwater and estuarine/marine waters) -- data requirements (no guideline reference) number (also, see 70-1 under ecological effects). Protocols are to be submitted and reviewed by the Agency before testing is initiated. Registrants should contact the Agency for references concerning this protocol.

(H) Develop DERs for Products on Emerging Nanotechnologies: Product Chemistry, And toxicology of these new and novel products.

Subtask 1-1-2: Review of Submissions and Identification of Data Gaps.

The contractor, in support of the 1988 FIFRA re-registration amendments and the FQPA amendments of 1996, shall review pesticide active ingredients to identify data gaps and any studies that indicate adverse effects. These reviews will consider subtask 1-1-1, or submissions and actual studies when necessary, or as directed by the Project Officer. The review report shall include generic data tables with appropriate footnotes and discussions regarding whether the adequacy of the data submitted is acceptable.

Subtask 1-1-2a

The contractor shall develop full science chapters on environmental Fate Risk Assessments and Risk Characterization based on primarily DER which were developed under Task 1-1-1

Task 1-2: Test Guideline Support

If OPP's review of its environmental fate chemistry Guidelines indicates a need for revisions, the contractor shall be required to conduct a state-of-the-science review of literature, characterizing test methodologies and science issues related to environmental fate, analyze current testing methodologies and guidelines, prepare recommendation reports regarding modification of current testing methodologies and guidelines, that will be reviewed by OPP and other experts. The contractor's effort may extend to providing technical support for international test guideline issues, including "harmonization" and international discussions and agreements (e.g., NAFTA). The contractor's participation in Test Guideline support is limited specifically to providing technical support.

Task 1-3: Conduct Backup Literature Search and Hard Copy Acquisition

On occasion, in performance of tasks 1-1, 1-2, or 1-4, the data furnished by OPP may have gaps that will have to be filled from open literature or private literature sources. Following EPA policies, the contractor shall identify any additional data needed to adequately characterize environmental fate. When OPP or the contractor identifies gaps that OPP deems are significant, the contractor shall conduct literature searches of approved data bases, and shall acquire literature for review of the assessment of environmental impacts of pesticides. The contractor shall provide to the project officer both hard and electronic copies of the literature listing resulting from the search, and hard copy of the literature acquired with the first draft of the related report.

Task 1-3-1

OPP will identify the relevant studies needed to fill the data gaps. The contractor shall develop DERs and full science chapters on the environmental fate and transport risk assessment and risk characterization

Task 1-4: Modeling, Models, Model Review and Development

When directed by the Contracting Officer, the contractor shall:

- (a) As directed, utilize Agency exposure models and or non-Agency models that Agency approves to determine concentrations of pesticides in nontarget aquatic sites, resulting from discharges from industrial sites;
- (b) As directed, utilize all available Agency and non-Agency exposure models to determine concentrations of pesticides (including wood preservatives, antifoulants,

cooling towers ,ballast water, and algaecides) in nontarget terrestrial and aquatic sites, resulting from proposed or registered uses;

- (c) As directed, review, examine, and compile all available Agency and non-Agency exposure models for determining concentrations of pesticides (including wood preservatives, antifoulants, and algaecides) in nontarget terrestrial and aquatic sites, resulting from proposed or registered uses;
- (d) As directed, assist the Agency in developing new, modified, or improved, exposure models for determining concentrations of pesticides (including wood preservatives, antifoulants, and algaecides) in nontarget terrestrial and aquatic sites, resulting from proposed or registered uses;
- (e) Provide electronic copies of models, their manuals and literature search results about the use of each model. The contractor shall also be prepared to compare actual and estimated data from models, and provide a summary of the gaps between the two sets of data (if any), and provide recommendations on how to close the gaps; and
- (f) Use variable data for running models; any estimated data should be verified with EPA before use.

Task 1-5: Workshops, Seminars, and Training

When directed by the Contracting Officer, the contractor shall identify recognized experts in the area of environmental fate and related areas, and with the Contracting Officer's approval, shall convene a meeting with such experts to resolve issues regarding environmental assessment guidelines. Additionally, the contractor shall prepare technical publications such as workshop summaries, minutes following seminars and other meetings.

TASK 2: ECOLOGICAL EFFECTS SUPPORT

This procurement will provide for assessments of ecological hazards associated with pesticide use, for registration and registration review activities. The procedures used by the Agency in testing and evaluating ecological risk are described in the Pesticide Assessment Guidelines for fish and wildlife (Subdivision E), non-target plants (Subdivision J), non-target insects (Subdivision L), Proposed Part 158, Subpart W, and microbial pest control agents (Subdivision M). Occasionally in addition to data evaluation the contractor may be requested to: 1) perform environmental risk calculations; 2) conduct literature searches and summarize the retrieved articles; 3) summarize incident reports of pesticide poisoning to non-target organisms; 4) review articles on endangered species, convene workshops and/or seminars; 5) assist the Agency in training activities; and 6) provide support on special projects.

Task 2-1: Registration and Registration Review Support

For the registration and registration review of specific pesticide products, including new uses for currently registered products and new pesticides, OPP has the responsibility of determining data gaps, reviewing ecological effects (hazards) data submitted with applications, developing environmental exposure/risk calculations, and determining potential risk-reduction effects of various mitigation measures. The contractor shall provide support for these activities, which may include statistical evaluation of ecological effects data, review of data submitted in support of registration and registration review and preparation of exposure and risk calculations which will include endangered species assessment and Magnusson-Stevens Act assessment, as discussed below under the various subtasks.

Subtask 2-1-1: Evaluation of Ecological Effects (Ecotoxicity) Data

Each ecological effects study for a pesticide shall be evaluated and reported as specified by the requirements of EPA's Antimicrobials Division's Data Evaluation Records (DERs). A sample set of DER formats for ecological effects endpoints are attached (Attachment 1). These formats shall be followed in the preparation of DERs. The data evaluation for each study will include: (1) an in-depth examination of the materials and methods employed, (2) an in-depth examination of the reported results, (3) an in-depth discussion of the reviewer's scientific assessment of the study, and (4) the reviewer's conclusions which summarize the overall significance of the study. The review and evaluation of each study will include a review and analysis of all necessary graphic displays of data, summary tables, and references needed to substantiate technical detail supporting the reviewer's conclusions. All DER's must be signed and dated. For each chemical, the data submitted may include any or all of the following studies (Numbers refer to specific test guidelines published as part of the Pesticide Assessment Guidelines), (the 6 Basic Studies are in Bold):

70-1 Special studies (e.g., cholinesterase inhibition, dermal toxicity, biomonitoring, monitoring)

850.2100/71-1(a) **Acute Avian Oral, Quail/Duck**
850.2100/71-1(b) Acute Avian Oral, Quail/Duck (TEP)
850.2200/71-2(a) **Acute Avian Diet, Quail**
850.2200/71-2(b) **Acute Avian Diet, Duck**
850.2400/71-3 Wild Mammal Toxicity
850.2300/71-4(a) Avian Reproduction Quail
850.2300/71-4(b) Avian Reproduction Duck
850.2500/71-5(a) Simulated Terrestrial Field Study
850.2500/71-5(b) Actual Terrestrial Field Study
850.1075 /72-1(a) **Acute Fish Toxicity Bluegill**
850.1075 /72-1(b) Acute Fish Toxicity Bluegill (TEP)
850.1075 /72-1(c) **Acute Fish Toxicity Rainbow Trout**

850.1075 /72-1(d) Acute Fish Toxicity Rainbow Trout (TEP)
850.1010 /72-2(a) **Acute Aquatic Invertebrate Toxicity**
850.1010 /72-2(b) Acute Aquatic Invertebrate Toxicity (TEP)
850.1075 /72-3(a) Acute Estuarine/Marine Toxicity Fish
850.1025;850.1055/72-3(b) Acute Estuarine/Marine Toxicity Mollusk
850.1035;1045/72-3(c) Acute Estuarine/Marine Toxicity Shrimp
850.1075 /72-3(d) Acute Estuarine/Marine Toxicity Fish (TEP)
850.1025;850.1055 /72-3(e) Acute Estuarine/Marine Toxicity Mollusk (TEP)
850.1035;1045/72-3(f) Acute Estuarine/Marine Toxicity Shrimp (TEP)
850.1400 /72-4(a) Early Life-Stage Fish, Freshwater
850.1400 /72-4(a) Early Life-Stage Fish, Estuarine/Marine
850.1300/72-4(b) Life-Cycle Aquatic Invertebrate, Freshwater
850.1300/72-4(b) Life-Cycle Aquatic Invertebrate, Estuarine/Marine
850.1500/72-5 Life-Cycle Fish, Freshwater
850.1500/72-5 Life-Cycle Fish, Estuarine/Marine
850.1710; 850.1730; 850.1850/72-6 Aquatic Organism Accumulation
850.1950/72-7(a) Simulated Aquatic Field Study
850.1950/72-7(b) Actual Aquatic Field Study
850.1735/73-1 Whole Sediment-Acute Invertebrates, Freshwater
850.1735/73-1 Whole Sediment-Acute Invertebrates, Freshwater (TEP)
850.1740/73-2 Whole Sediment-Acute Invertebrates, Marine
850.1740/73-2 Whole Sediment-Acute Invertebrates, Marine (TEP)
NGN/73-3 Acute Pore Water, Fish and Invertebrates
NGN/73-3 Acute Pore Water, Fish and Invertebrates (TEP)
NGN/74-1 Whole Sediment-Chronic Invertebrates
NGN/74-1 Whole Sediment-Chronic Invertebrates (TEP)
850.4100/122-1(a) Seed Germination/Seedling Emergence (Tier I)
850.4150/122-1(b) Vegetative Vigor (Tier I)
850.4400; 850.5400/122-2 Aquatic Plant Growth (Tier I)
850.4225/123-1(a) Seed Germination/Seedling Emergence (Tier II)
850.4250/123-1(b) Vegetative Vigor (Tier II)
850.4400; 850.5400/123-2 Aquatic Plant Growth (Tier II)
850.4300/124-1 Terrestrial Field Study (Tier III)
850.4450/124-2 Aquatic Field Study (Tier III)
850.3020 /141-1 Honey Bee Acute Contact
850.3030 /141-2 Honey Bee Residue on Foliage
850.3040 /141-5 Field Test for Pollinators

EPA's Office of Water Studies, e.g.:
Freshwater Fish Acute Subchronic
Freshwater Invertebrate Acute Subchronic
Estuarine Fish Acute Subchronic
Estuarine Invertebrate Acute Subchronic

Subtask 2-1-2: Development of Ecological Effects (Ecotoxicity) Profiles and Tables Based On Pesticide Toxicity Data.

Based upon the DERs developed by the contractor, the contractor shall develop draft ecological effects (ecotoxicity) profiles and tables, utilizing formats provided by the Agency. Upon review and Agency acceptance of contractor reviewed DERS, the contractor shall develop final toxicity profiles and ecotoxicity tables, utilizing formats provided by the Agency.

Subtask 2-1-3: Review of Submissions and Identification of Data Gaps.

The contractor in support of the 1988 FIFRA registration amendments and the FQPA amendments of 1996, shall review pesticide active ingredients to identify data gaps and any studies that indicate adverse effects. These reviews will consider subtasks 2-1-1 and 2-1-2 submissions and actual studies when necessary or as directed by the Project Officer. The review report shall include generic and product-specific data tables with appropriate footnotes and discussions regarding whether the adequacy of the data submitted is acceptable.

Subtask 2-1-4: Determination of Environmental Exposure Scenarios

The contractor shall review information to determine what probable exposure scenarios exist for both nontarget terrestrial and aquatic organisms, and for endangered species. Such information will include use sites; frequency of use; rates of application; formulation and packaging types; equipment and techniques employed for mixing, loading and application; cultural practices associated with each use site; and terrestrial and aquatic organisms likely to be exposed, as well as possible routes of exposure (i.e., dermal, inhalation, oral, ocular).

The contractor shall review available literature supplied by the Office of Research and Development (ORD) (ECOTOX), and shall prepare an abbreviated record of each study [Environmental Fate and Effects Division (EFED) mini-DER form is available] as to why or why not the Agency used the study in its risk assessment. The contractor shall identify endangered species at risk through LOCATES and Fish and Wildlife Service/National Oceanic and Atmospheric Administration (FWS/NOAA) sources and review and summarize public comments. The contractor shall consult with the services, states, regions, etc. to identify species at risk and the action areas and develop a data base similar to EFED's LOCATES. The contractor shall develop a data base of maps for our use that are specific to treated wood use, once-thru cooling towers, antifoulants, ballast water discharges, etc. The contractor shall develop brochures to be posted on the web with mitigation buffers, etc. (similar to EFED's efforts). Additionally, the contractor shall review and assess chemical impacts on essential fish habitat (Magunssen-Stevens Act/NOAA). The contractor shall take and receive comments on meeting notes from meetings with the services, states, regions, etc.

The format for analysis should include the following:

Use Characterization

- B. Exposure Characterization
 - 1. Environmental Fate and Transport Characterization
 - 2. Measures of Aquatic Exposure
 - a. Aquatic Exposure Modeling
 - b. Aquatic Exposure Monitoring and Field Data
 - 3. Measures of Terrestrial Exposure
 - a. Terrestrial Exposure Modeling
 - b. Residue Studies
- C. Ecological Effects Characterization
 - 1. Aquatic Effects Characterization
 - a. Aquatic Animals
 - (1). Acute Effects
 - (2). Chronic Effects
 - (3). Sublethal Effects
 - (4). Field Studies
 - b. Aquatic Plants
 - 2. Terrestrial Effects Characterization
 - a. Terrestrial Animals
 - (1). Acute Effects
 - (2). Chronic Effects
 - (3). Sublethal Effects
 - (4). Field Studies
 - b. Terrestrial Plants
- D. Develop appendices:
 - 1. Aquatic Exposure Model and Results
 - 2. TREX model and Results
 - 3. TerrPlant Model and Results
 - 4. The Risk Quotient Method and Levels of Concern
 - 5. Detailed Risk Quotients.

Subtask 2-1-5: Environmental Exposure/Risk Characterization

The contractor shall review chemical ecotoxicity and use background information to make a preliminary determination as to whether EPA's ecological effects assessment criteria have been triggered. These criteria include: (1) if certain toxicological endpoints have been identified for the active ingredient; and (2) if there is potential exposure to nontarget organisms (e.g., fish, birds, wildlife) following applications. The contractor will use EPA mammalian toxicological and ecological effects reviews provided by EPA's Project Officer, along with product labels, Label Use Information System (LUIS) reports, and its knowledge of probable handling and application exposure situations to determine if such criteria are triggered for each registered use of an active ingredient.

The contractor shall use the data from subtasks 5-1-1 through 5-1-4 to calculate baseline risk, expressed as risk quotients (RQs), which are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic:

$$RQ = \text{EXPOSURE/TOXICITY}$$

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) acute high - potential for acute risk is high regulatory action may be warranted in addition to restricted use classification (2) acute restricted use - the potential for acute risk is high, but this may be mitigated through restricted use classification (3) acute endangered species - the potential for acute risk to endangered species is high regulatory action may be warranted, and (4) chronic risk - the potential for chronic risk is high regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds) (2) LD50 (birds and mammals) (3) EC50 (aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates) (2) NOEC (birds, fish and aquatic invertebrates) and (3) MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement end point is production of offspring or survival.

Risk presumptions, along with the corresponding RQs and LOCs will be provided by the WAM to the contractor.

The format for the risk characterization should include the following:

- A. Risk Estimation - Integration of Exposure and Effects Data
 - 1. Non-target Aquatic Animals and Plants
 - 2. Non-target Terrestrial Animals
 - 3. Non-target Terrestrial and Semi-aquatic Plants

- B. Risk Description
 - 1. Risks to Aquatic Organisms
 - a. Animals
 - b. Plants
 - 2. Risks to Terrestrial Organisms
 - a. Animals
 - b. Plants
- C. Description of Assumptions, Limitations, Uncertainties, Strengths and Data Gaps
 - 1. Assumptions, Limitations, Uncertainties, Strengths and Data Gaps Related to Exposure for All Taxa
 - 2. Assumptions, Limitations, Uncertainties, Strengths and Data Gaps Related to Exposure for Aquatic Species
 - 3. Assumptions, Limitations, Uncertainties, Strengths and Data Gaps Related to Exposure for Terrestrial Species
 - 4. Assumptions, Limitations, Uncertainties, Strengths and Data Gaps Related to Effects Assessment
 - 5. Assumptions, Limitations, Uncertainties, Strengths and Data Gaps Related to the Acute and Chronic LOC's

Task 2-2: Test Guideline Support

If OPP's review of its Subdivision E Pesticide Assessment Guidelines indicates a need for revisions, the contractor shall be required to conduct a state-of-the-science review of literature, characterizing test methodologies and science issues related to ecological effects, analyze current testing methodologies and guidelines, prepare recommendation reports regarding modification of current testing methodologies and guidelines, that will be reviewed by OPP and other experts. The contractor's effort may extend to providing technical support for international test guideline issues, including "harmonization" and international discussions and agreements (e.g., NAFTA). The contractor's participation in Test Guideline support is limited specifically to providing technical support.

Task 2-3: Review of Incident Information

The Agency, on an ad hoc basis, receives information on the effects of pesticides on non-target organisms or pesticide residues in the environment. The contractor shall do a summary of the findings as well as an appraisal of the completeness of the report. The work assignment will provide the level of detail expected in the final evaluation.

Task 2-4: Conduct Backup Literature Search and Hard Copy Acquisition

On occasion, in performance of Tasks 5-1 through 5-3 noted above, the data furnished by OPP may have gaps that will have to be filled from open literature or private literature sources. Following EPA policies, the contractor shall identify any additional data needed to adequately

characterize ecological effects. When OPP or the contractor identifies gaps that OPP deems are significant, the contractor shall conduct literature searches of approved data bases, and shall acquire literature for review of the assessment of ecological effects of pesticides. The contractor shall provide to the project officer both hard and electronic copies of the literature listing resulting from the search, and hard copy of the literature acquired with the first draft of the related report.

Task 2-5: Workshops, Seminars, and Training

When directed by the Contracting Officer, the contractor shall identify recognized experts in the area of ecological effects and related areas, and with the Contracting Officer's approval, shall convene a meeting with such experts to resolve issues regarding ecological issues and ecological assessment guidelines. Additionally, the contractor shall prepare technical publications such as workshop summaries, minutes following seminars and other meetings.

Task 2-6: Special Assignments

In addition to performing the tasks identified above for Registration Actions and Registration Standards, the contractor may be asked to perform special assignments. These generally include an assessment of data, a review of protocols submitted to EPA in support of higher tier testing requirements, or reviewing comments on endangered species activities. Other assignments related to the development and revision of protocols, guidelines and standard evaluation procedures may be required.

TASK 3: INTEGRATION OF SCIENCE PRODUCTS SUPPORT

For registration, registration review, or special projects, the contractor may be asked by the Agency to provide technical support for the summarization and compilation of science products produced under tasks 1 - 2. Using formats provided by the EPA WAM, the contractor will collate and summarize data, tables, or discussions on: fate chemistry; ecotoxicology; environmental exposures and risks; data gaps and data requirements; environmental risk mitigation measures; and bibliographies or citations. For each assigned pesticide chemical, the contractor shall provide this summary in written and electronic formats, including all pertinent information as outlined above.

IX. DELIVERABLES

All reports shall be provided in Microsoft Office Word format, both electronically and in paper copy. The contractor shall also provide disk copies of any appropriate spreadsheets or databases created under this work assignment, copies of models, literature and correspondence referenced in revised reports. In addition to Monthly Progress Reports, the Contractor shall meet the schedule listed below. The due dates are to be met unless otherwise specified by the Work Assignment Manager. Changes to the due dates listed below will involve consultations with the contractor and will consider the total estimated hours for each work assignment.

Deliverable	Due Date
Work Plan	15 days after WA received
Draft DER	15 days (or as specified in Task Assignment by PO or WAM)
Final DER	7 days after draft report submitted to contractor
Literature Search Listing	15 days after receiving the Task Assignment
Literature (hard copies)	As specified in Task Assignments by PO or WAM
Tasks and Subtasks	As specified in Task Assignments by PO or WAM (The due dates will vary depending on the discipline)

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 3-05								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-W-11-020	Contract Period 02/01/2011 To 01/31/2015 Base Option Period Number 3	Title of Work Assignment/USF Site Name DER Production AD								
Contractor CDM FEDERAL PROGRAMS CORPORATION		Specify Section and paragraph of Contract SOW Section III Task A								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval		Period of Performance From 02/01/2014 To 01/31/2015								
Comments: The purpose of this action is to approve the contractor work plan and cost estimate dated February 27, 2014.										
<input type="checkbox"/> Superfund		Accounting and Appropriations Data								
		<input checked="" type="checkbox"/> Non-Superfund								
SFO (Max 2) <input type="checkbox"/>		Note: To report additional accounting and appropriations data use EPA Form 1900-69A.								
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		\$0.00		LOE:		0		
02/01/2011 To 01/31/2015										
This Action:				\$57,650.49				750		
Total:				\$57,650.49				750		
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		02/27/2014		Cost/Fee:		\$57,650.49		LOE:		750
Cumulative Approved:				Cost/Fee:		\$57,650.49		LOE:		750
Work Assignment Manager Name		Srinivas Gowda				Branch/Mail Code:				
						Phone Number 703-308-6354				
						FAX Number:				
						Branch/Mail Code:				
						Phone Number: 703-305-6937				
						FAX Number:				
Other Agency Official Name						Branch/Mail Code:				
						Phone Number:				
						FAX Number:				
Contracting Official Name		Christine Edwards				Branch/Mail Code:				
						Phone Number: 202-564-2182				
						FAX Number:				